

AUG 26 2004

K041419

510 K General Summary

The **LIGHTFORCE** 20/30 980nm Diode Surgical Laser is intended to provide the physician with a dependable laser system providing he/she the ability to incise, excise, vaporize and coagulate soft tissue in a variety of surgical procedures in various disciplines as listed:

Dermatology
ENT/Head & Neck
Gynecology

Gastroenterology
General Surgery
Neurosurgery

Pulmonary
Urology
Proctology

The **LIGHTFORCE** 20/30 980nm Diode Surgical Laser for soft tissue applications is accompanied by a variety of disposable fiber optic delivery systems for use in the different specialties. Each are compatible to all popular endoscopes and laparoscopes on the market. A variety of Disposable Fiber Optic Delivery Systems are available for performing open and endoscopic surgical procedures with the **LIGHTFORCE** 20/30 980nm Diode Surgical Laser System for achieving incision, excision, vaporization and coagulation on soft tissue applications.

These disposable fiber optic delivery systems are available in various sizes (200, 400, 600, and 1000 micron) for performing contact and non-contact laser surgery techniques by the operating physician to assist in achieving Incision/Excision/Vaporization/Coagulation at **CONTROLLABLE** depths of tissue penetration from 0.3mm up to 4mm.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2004

Mr. David P. Lewing
Director of Regulatory Affairs
Medical Energy, Inc.
225 E. Zaragoza Street
Pensacola, Florida 32502

Re: K041419
Trade/Device Name: LIGHTFORCE 20/30 980nm Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 25, 2004
Received: May 28, 2004

Dear Mr. Lewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

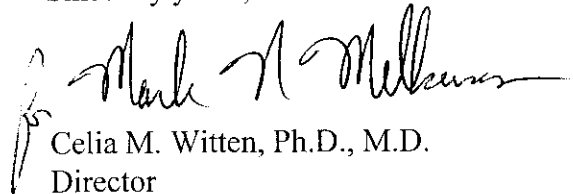
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number: K041419

Device Name: LIGHTFORCE 20/30 980nm Diode Laser

Indications For Use:

1. For soft tissue Incision, Excision, Vaporization and Coagulation:

- | | |
|--------------------|-------------------|
| * Gastroenterology | * Neurology |
| * General Surgery | * Urology |
| * Gynecology | * Pulmonary |
| * ENT/Head & Neck | * Plastic Surgery |

Including:

- * Gynecology-Endometrial Ablation (K871512)
- * Urology Surgery (K871516)
- * Rectal Patho. & Hemorrhoid (K871514)
- * Gastro Intestinal Bleeding (K871515)
- * Palliation of Gastro Malignancies (K871513)
- * Pulmonary Obstructions (K871511A)

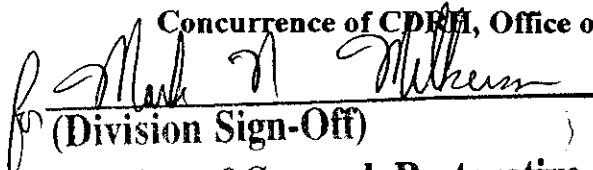
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDREH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041419